

**Remarks**

Claims 1-20 are pending in this application. New Claims 15-20 are being added. Support for new claims 15-20 can be found in the specification as originally filed. No new matter has been added.

**Rejections under 35 USC 102(e)**

1. Rejection of Claim 14 under 35 USC 102(e) as anticipated by Yamamoto (US Pat No. 6,312,410).

Claim 14 stands rejected under 35 USC 102 as being anticipated by Yamamoto.

The Office Action indicates that "Yamamoto discloses a syringe having a body 2, plunger 3 and at least one attachment member 3 and at least one rotation member 101."

It is well settled that in order for a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in prior art. The disclosure requirement under 35 USC 102 presupposes knowledge of one skilled in the art of the claimed invention, but such presumed knowledge does not grant license to read into prior art reference teachings that are not there. See Motorola Inc. v. Interdigital Technology Corp. 43 USPQ2d 1481 (1997 CAFC).

Regarding the Office Action's allegation that Yamamoto discloses "at least one rotation member 101," Yamamoto discloses a piston 3 disposed in the cylindrical body part 6 of the syringe 2. Col 2, lines 39-44. A piston adaptor 100 for connecting the piston 3 to the injection head 10. Col. 4, lines 54-59. The piston adaptor includes a rotation member 101 including an oval window part 101b which can receive a head portion 11a (see Fig. 14) of the same shape as the window part 101b provided on the connection part of the plunger 11. Col 4, line 66 to Col 5, lines 1-3. The rotation member 101 is further provided on its other end with an opening window 101e that can receive the core member 102. Col 5, lines 6-9. Thus in Yamamoto, rotation member 101 merely connects

plunger 11 to the piston adaptor and is not formed in the body of the syringe, but rather included in a piston adaptor 100 separate from the syringe. Accordingly, Yamamoto does not include "at least one rotation member comprising a recess formed in the body for releasably engaging a corresponding member of the syringe retaining mechanism of the injector," as recited in independent Claim 14.

Regarding the Office Action's allegation that Yamamoto discloses "at least one attachment member 3," the piston 3 of Yamamoto, is not associated with the body, but is disposed within the body to provide an internal space that is defined by the piston 3. Col. 2, lines 36-38. Thus, Yamamoto discloses a piston, and does not disclose an "attachment member associated with the body" of Applicants' invention of Claim 14.

Therefore Yamamoto does not disclose *each and every limitation* of independent Claim 14, and Applicants respectfully request reconsideration of the rejection of Claim 14.

### Rejections under 35 USC 103

#### 2. Rejection of Claims 1-13 under 35 USC 103(a) as being unpatentable over Yamamoto in view of Reilly (US Pat No. 5,383,858).

The Office Action indicates that:

Yamamoto discloses a syringe body 2, plunger 3, attachment member 5, annular ridge, tab member 5 and flange 5. In reference to Claim 3, Yamamoto discloses a projection 101. In reference to Claim 11, it is considered that the attachment member may [be] moved vertically depending on the position to the injector. Further, the Office Action indicates that Yamamoto does not disclose an encoding device. Reilley discloses an encoding device on a syringe... It would have been obvious to one of ordinary skill in the art to modify the invention of Yamamoto, by including an encoding device, as suggested by Rilley, in order to prevent misdose of medicine to a patient.

It is well settled that to establish a *prima facie* case of obviousness, the USPTO must satisfy all of the following requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated

the skilled artisan to modify a reference or to combine references. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification does not have a reasonable expectation of success, as determined from the vantage point of one of ordinary skill in the art at the time the invention was made. *Amgen v. Chugai Pharmaceutical Co.* 18 USPQ 2d 1016, 1023 (Fed Cir, 1991), cert. denied 502 U.S. 856 (1991). Third, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496, (CCPA 1970).

Yamamoto discloses one embodiment of a syringe and one embodiment of an injector including a syringe adaptor 200. Specifically, Yamamoto discloses a syringe 2 with a flange part 5 that is provided on the rear end for defining an opening. Col 2, lines 31 – 34. Also, Yamamoto discloses that a flange receiving part 203 supports the flange part 5 of the syringe 2 from the rear end and the outer side surface, and a pair of holding members 204 and 205 cover the flange part 5 from the front end of the syringe 5 Col 6, lines 7-12. Therefore, the flange part 5 of Yamamoto, not only merely defines an opening of the syringe, but also is formed to be supported by the flange receiving part 203.

Further, the one embodiment of injector syringe adaptor 200 requires that the position of the syringe relative to the injector is limited to one orientation. Yamamoto discloses that a structure of the syringe adapter 200 includes holding members 204, 205 that open in a horizontal direction (see Figs. 6 and 7). The holding members 204 and 205 are provided with slots for 204b and 205b for limiting open states thereof. Col 6, 20-23. Further, Yamamoto only discloses one structure for the flange part 5 of the syringe 2, and the holding members 204, 205 rotate independently of the flange part 5. As shown in Fig. 1, the syringe includes the two extending flange parts 5 that are oriented to be held by holding members 204, 205, whereas the “flattened portions” between the extended flange parts 5 are not wide enough to be held by the holding members 204, 205. Accordingly, the position of the syringe and injector (including syringe adaptor 200) is limited to one orientation such that the flange part 5 may be inserted and supported by holding members 204 and 205. Thus, the syringe of Yamamoto

must be rotated to a specific axial position with respect to the injector so that the flange is aligned with the opening formed by the rotation of the holding members 204, 205, and is not independent of the orientation with respect to the injector.

Further, the Office Action alleges that Yamamoto discloses an "attachment member 5," however, the flange part 5 of Yamamoto is not adapted to releasably engage the syringe retaining mechanism of the injector. In fact, the syringe of Yamamoto is not adapted for any releasing engagement, rather the holding members 204, 205 are rotatably fixed to the syringe adaptor, and the syringe adaptor includes a first lever 201 that provides the rotation of the holding members 204, 205 to cause releasing of the flange part 5. Col. 6, lines 15-48. In Yamamoto, the syringe is not adapted to assist in any releasing of the syringe adaptor.

Thus, Yamamoto does not disclose the "at least one attachment member adapted to releasably engage the syringe retaining mechanism of the injector regardless of the orientation of the syringe with respect to the injector" of Applicants' invention of independent Claim 1.

Regarding Claim 3, Yamamoto does not teach or suggest projections of Applicants' invention. Yamamoto describes a piston adaptor 101, as discussed above, including a rotation member 101 that merely connects the plunger with the piston. Col 5, lines 46-48. The rotation member 101 is not associated with the body of the syringe. Thus, Yamamoto does not teach or suggest a syringe including "one or more projections associated with the body, the one or more projections adapted to enable release of the syringe from the injector through rotation motion."

Regarding Claim 11, the Office Action alleges that Yamamoto teaches "the attachment member may [be] moved vertically depending on the position of the injector" (*emphasis added*). However, Applicants' invention of Claim 1 is directed to an "attachment member adapted to releasably engage the syringe retaining mechanism of the injector regardless of the orientation of the syringe with respect to the injector." Therefore, Yamamoto teaches away from Applicants' invention by requiring that, as alleged in the Office Action the

"attachment member 5" of the syringe may be moved depending on the position of the injector, which is indicative of requiring a specific orientation of the syringe with respect to the injector. Further, Claim 11 depends from and adds further limitations to Claim 1.

Additionally, the combination of Yamamoto and Reilly fail to teach or suggest all of the limitations of amended independent Claim 1. Yamamoto does not teach or suggest independent Claim 1, and the disclosure of Reilly fails to cure this deficiency. Therefore, these references cannot be used in combination as the basis of a 35 USC 103(a) rejection.

Further, Claims 2-13 either directly or indirectly depend from and add further limitations to Claim 1 and are deemed allowable for at least the same reasons in combination with independent Claim 1. Reconsideration is respectfully requested.

### **NEW CLAIMS**

New independent claims 15-20 are directed to a syringe for use with an injector comprising a syringe retaining mechanism, the syringe comprising:

a body comprising a rear end and a front end;

a plunger movably disposed within the body;

at least one attachment member disposed on and extending from the body, the at least one attachment member adapted to releasably engage the syringe retaining mechanism of the injector regardless of the orientation of the syringe with respect to the injector; and

an encoding device operable to provide syringe information to the injector.

Applicants' invention provides that:

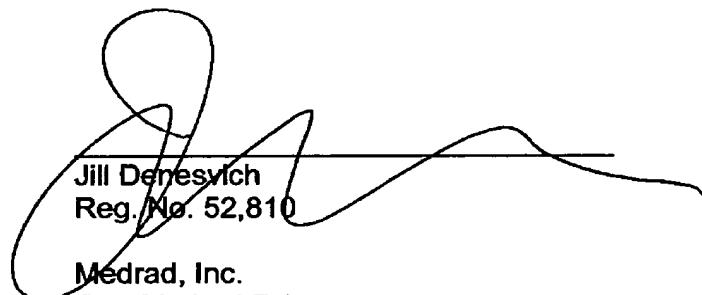
The at least one attachment member is disposed on and extends from the body of the syringe, for example see Fig. 55 as a non-limiting example.

Regarding new Claims 16-20, Claims 16-20 depend from new independent Claim 10, which as discussed are believed to be allowable. Accordingly, Claim 16-20 also are believed to be allowable.

In view of the above amendments and remarks, Applicants submit that the claims are in condition for allowance and the Examiner would be justified in allowing them.

Respectfully submitted,

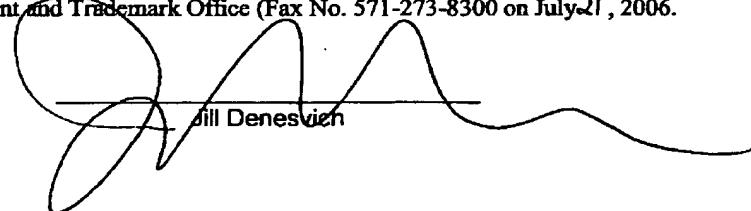
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